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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,247	01/30/2004	Daniel J. Capon	P0444PIC7	8092
9157	7590	12/13/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/769,247

Applicant(s)

CAPON ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 14-16, 50-57, 60, drawn to a DNA encoding a CD4 variant of an adhesion, classified in class 536, subclass 23.5.
- II. Claims 1, 2, 5-16, 17-25, 41-58, and 60, drawn to a DNA encoding fusion CD4 variant and polypeptide fusion variants, classified in class 536, subclass 23.5.
- III. Claims 24-40, drawn to a CD4 variant, classified in class 530, subclass 350.
- IV. Claim 59, drawn to a method of treatment of an HIV infection comprising administering therapeutic dose of an amino acid variant of CD4 to a patient infected with HIV, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

The polynucleotides and polypeptides of group I- III are patentably distinct inventions for the following reasons. Groups I, II and III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Polypeptides, which are composed of amino acids, and

polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The DNA of group I can be used other than to make the protein of Group III, such as in gene therapy or as a probe in nucleic acid hybridization assays. The polynucleotides of Groups I and II are unrelated and encode structurally and functionally diverse polypeptides. Finally, the polypeptides of Groups II-III are composed of different purine and pyrimidine units. The polypeptide of Group II is a fusion protein, comprising a CD4 polypeptide and another polypeptide. The polypeptide of Group III is simply an adhesion protein variant.

Furthermore, searching the inventions of groups I, II and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I-II and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case polypeptide of Invention II could be used to prepare antibody for diagnostic assays.

Searching the inventions III and IV together would impose serious search burden. The inventions of III and IV have a separate status in the art as shown by their different classifications. Moreover, the search for an adhesion polypeptide and the methods of treating a disease with an adhesion peptide are not coextensive.

Inventions I-II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated. For example, the claimed methods IV do not recite the use or production of polynucleotide or polypeptide from Group I-II.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

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found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A. Polypeptide different from CD4 to make adhesion polypeptide:

- i) a non-CD4 immune epitope
- ii) a signal peptide
- iii) a viral peptide
- iv) a human plasma protein
- v) albumin
- vi) apolipoprotein
- vii) transferrin
- viii) a cytotoxic peptide
- ix) diphtheria toxin A

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 5, 25 and 44 are generic.

B. A variant protein is:

x) CD4 residues 1-368 (v1-v4)

xi) CD4 residues 1-180 (v1-v2)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, and 15 are generic.

C. An adhesion is:

xii) CD4

xiii) CD8

xiv) IgE receptor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 is generic.

D. Adhesion amino acid sequence variant is:

xv) AC<sub>L</sub>

xvi) AC<sub>L</sub>-AC<sub>L</sub>

xvii) AC<sub>H</sub>-AC<sub>H</sub>

xviii) AC<sub>H</sub>-AC<sub>L</sub>-AC<sub>H</sub>

xix) AC<sub>H</sub>-AC<sub>L</sub>-V<sub>H</sub>C<sub>H</sub>

xx) AC<sub>H</sub>-V<sub>L</sub>C<sub>L</sub>-AC<sub>H</sub>

xxi) AC<sub>H</sub>-V<sub>L</sub>C<sub>L</sub>-V<sub>H</sub>C<sub>H</sub>

xxii) AC<sub>L</sub> - AC<sub>H</sub> - AC<sub>H</sub>

xxiii) AC<sub>L</sub> - AC<sub>H</sub> - AC<sub>L</sub> - AC<sub>H</sub>

xxiv) AC<sub>L</sub> - AC<sub>H</sub> - AC<sub>L</sub> - V<sub>H</sub>C<sub>H</sub>

xxv)  $AC_L - AC_H - V_L C_L - AC_H$   
xxvi)  $AC_L - AC_H - V_L C_L - V_H C_H$   
xxvii)  $AC_L - V_H C_H - AC_H$   
xxviii)  $AC_L - V_H C_H - AC_L - AC_H$   
xxix)  $AC_L - V_H C_H - AC_L - V_H C_H$   
xxx)  $AC_L - V_H C_H - V_L C_L - AC_H$   
xxxi)  $AC_L - V_H C_H - V_L C_L - V_H C_H$   
xxxii)  $V_L C_L - AC_H - AC_H$   
xxxiii)  $V_L C_L - AC_H - AC_L - AC_H$   
xxxiv)  $V_L C_L - AC_H - AC_L - V_H C_H$   
xxv)  $V_L C_L - AC_H - V_L C_L - AC_H$   
xxvi)  $V_L C_L - AC_H - V_L C_L - V_H C_H$   
xxvii)  $(A-Y) n- (V_L C_L - V_H C_H) 2$

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 24,25, and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**If Applicant selects either Invention I or II, one species from the Polypeptide different from CD4 group, one species from the variant protein group, and one species from an adhesion group must be chosen to be considered fully responsive. If Applicant selects Invention III, one species from the adhesion amino acid variants group must also be chosen to be considered fully responsive.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra  
AU 1646  
6 December 2004

  
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